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10/576,589	09/05/2006	David Malcolm Leathwick	JAMES68.015APC	7265

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EXAMINER	
BUCKLEY, AUDREA	

ART UNIT	PAPER NUMBER
4131	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/576,589	LEATHWICK ET AL.	
	Examiner	Art Unit	
	AUDREA BUCKLEY	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *(3) 10/25/2007, 5/31/2007, 4/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 4/21/2006, 5/31/2007, and 10/25/2007 were filed separately from the application filing date of 09/05/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Acknowledgement

Receipt of the International Search Report and International Preliminary Report on Patentability is acknowledged, and the contents of said reports have been considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 22 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an

improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 provides for the use of two or more anthelmintic compounds of differing chemical groups in the manufacture of a delivery device, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Claim 22 depends on Claim 21, which depends on Claim 1. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. The aforementioned language is interpreted as an additional or modification to the intended method of use as outlined in Claim 1.The examiner is unclear as to how this language further limits or defines the structure or elements of the medicament of Claim 1. Thus, the language of Claim 22 is, at a

minimum, indefinite, raising a question as to the metes and bounds of the claim and the scope of patent protection sought by the applicant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 10, 11, 14, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hennessy *et al.* (US 5,840,324) and as evidenced by Lau *et al.* (WO 2004/069242 A1).

Claim 1 is drawn to a method of reducing parasites in animals by introducing a single delivery device containing two or more different anthelmintic compounds to an animal; also, the delivery device is an intra-ruminal bolus configured to release an effective amount of active agents each day for a period of between 3 and 14 days.

Hennessy *et al.* teach a particulate composition for combating and preventing parasite infestation of ruminant animals. The anti-parasite composition comprises a benzimidazole, a macrocyclic lactone, as well as other agents, where all active components are dispersed in a medium such that the solubility characteristics of the composition ensure that, following oral administration, controlled amounts of the anti-parasite agent become available to

the parasite, either directly or by absorption into the ruminant blood plasma, during passage of the composition through the rumen (column 3, line 24). More specifically, Hennessy *et al.* show time release data which indicates that the active ingredient ivermectin, which was chosen as a representative active agent for time release function *in vivo* studies, was still being released after 80 hours, or 3.3 days (Figure 7, Sheet 7 of 11; column 5, line 59). As such, Hennessy *et al.* anticipated the instant invention as defined in Claim 1.

Regarding Claim 2, which is drawn to two or more anthelmintic compounds having different activities from one another, Hennessy *et al.* also anticipate this feature of the instant invention. Hennessy *et al.* teach the role of relative proportions in order for appropriate ruminal intake, where benzimidazole and macrocyclic lactones in general are considered. These two anthelmintic species are present in different quantities (40 g benzimidazole and 100 mg macrocyclic lactone) with different target ratio presences in the overall composition (column 5, line 36; column 6, see Example 1). Therefore, Hennessy *et al.* anticipated the content of Claim 2.

While claim 4 is drawn to the reduction in the parasite burden on an animal as the result of the method including at least two or more active agents, and while Hennessy *et al.* teach methods towards the reduction of the parasite burden on an animal, Hennessy *et al.* do not actually state that the formulation as a whole proves effective at terminating the target parasites. However, Lau *et al.* also teach anthelmintic compositions comprising benaimidazoles, macrocyclic lactones, and a therapeutically acceptable carrier, among other components in

order to utilize a synergistic anthelmintically active anti-parasite composition. With regard to the instant claim, Lau *et al.* expressly state the efficacy of the disclosed methodology as one embodiment demonstrates "excellent control (>99.9% reduction) or a mixed gastrointestinal strongly burden as assessed" (page 17, paragraph 1). That is, the reduction in the parasite burden on an animal necessarily would happen upon application of the anthelmintic compositions. So, Hennessy *et al.* anticipate the reduction of the parasite burden by implementing anthelmintic ingredients as evidenced by Lau *et al.*

While claim 5 is drawn to the reduction in the number of resistant parasites in the animal, Hennessy *et al.* teach the invention which “leads to the elimination of up to 30% more benzimidazole-resistant worms than is achieved by the same dosage of a conventional benzimidazole preparation," (column 6, line 24); therefore, Hennessy *et al.* anticipated the content of the instant claim.

Regarding Claim 6, which is drawn to groups of anthelmintic compounds deemed desirable as active agents in the instantly claimed composition, Hennessy *et al.* anticipate these types of functional components as evidenced by the citation of Nematodirus as a disclosed example of macrocyclic lactone antiparasitic agents (column 4, line 6).

Likewise, the macrocyclic lactone identity of chosen anthelmintic compounds as named in instant Claim 7 is anticipated by the Teachings of Hennessy *et al*, which claim macrocyclic lactones in particular (column 9, line 28). Claim 8 limits the identity of the macrocyclic lactone to abamectin; Hennessey *et al.* previously claimed abamectin as a specific macrocyclic lactone

for use in the analogous anti-parasite composition (column 10, line 51). Claims 10 and 11 are drawn to benzimidazole as the anthelmintic compound and to albendazole as the benzimidazole species. Hennessy *et al.* previously taught both of these active agents in the analogous composition (column 9, line 47).

Claim 14 is drawn to the method of use as applied to sheep; Hennessy *et al.* taught anti-parasitic formulations to be undertaken with sheep (column 6, line 22), thereby anticipating the content of Claim 14.

Claim 17 is limits the parasite to one which is an endoparasite selected from a listing of groups of endoparasites. Hennessy *et al.* anticipate anti-parasite activity with respect to nematodes as evidenced by the fact that Nematodirus explicitly is named as a species against which not only the benzimidazole agent is active (column 3, line 60), but also against which the macrocyclic lactone agent is active (column 4, line 6), among others.

Regarding Claim 19 which limits the delivery device to one which is a controlled release device, Hennessy *et al.* disclose a composition which is dispersed in a proteinaceous matrix which undergoes staged degradation allowing controlled release of the anti-parasitic agent (column 5, line 15); therefore, Hennessy *et al.* anticipated the controlled release feature of the instant invention.

Therefore, it is shown that Hennessy anticipated the content of instant Claims 1, 2, 4-8, 10, 11, 14, 17, and 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 3, 20, 21, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennessy *et al.* (US 5,840,324) in view of Whitehead (US 6,030,637).

Claims 1 and 2 are rejected for the reasons set forth in the 102 rejection above.

Claim 1 is drawn to a method of reducing parasites in animals by introducing a single delivery device containing two or more different anthelmintic compounds to an animal

Regarding claims 3 and 25 which limit the release of the active agents to a rate which is substantially continuous, Hennessey *et al.* do not elaborate upon release studies. Relevantly, however, Whitehead teaches a bolus for the administration of biologically active material to ruminants. The invention which Whitehead discloses includes boli with variable corrosion characteristics which in turn degrade or corrode to release the active material. More specifically, Whitehead teaches the option of utilizing boli which release the active agent continuously with time (column 1, line 19). Due to the necessity of an effective delivery system for the anthelmintic active agents of the instant invention, one of

ordinary skill in the art at the time of the invention would have been motivated to combine the pellet teachings of Whitehead with the anthelmintic antiparasitic compositions as taught by Hennessy *et al.* Similarly, claims 20 and 21 are drawn to the bolus delivery device and its features. While Claim 20 is drawn to a delivery device which delivers a maximum integral dose, Whitehead teaches a bolus comprising a plurality of discrete bolus elements, each element having a degradable outer sheath and a core of the active formulation (column 2, line 18). While claim 21 is drawn to any delivery device for the controlled release of the active agents, Whitehead's teachings render the bolus as a *prima facie* obvious device for this function, particularly since Whitehead's bolus is one designed especially to deposit active agents to a ruminant (column 1, line 19; column 1, line 26).

One of ordinary skill in the art reasonably would have expected continued success from the implementation of not only anthelmintic agents into a bolus but also for selecting an bolus appropriate for the desired release as taught by Whitehead and Hennessey *et al*. Therefore, one of ordinary skill in the art at the time the invention was made would have found the combination of these references to have been *prima facie* obvious.

Claims 1 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennessy *et al.* (US 5,840,324).

Claims 1, 7, and 8 are rejected for the reasons set forth in the 102 rejection above.

Regarding the dosage of the abamectin macrocyclic lactone as limited by claims 9 to an amount between 0.1 to 0.2 mg/kg/day, one of ordinary skill in the art would have found the optimization of a dosage range to have been routine experimentation procedure and therefore *prima facie* obvious over the teachings of Hennessey *et al.* which detail the functional role of abamectin as a macrocyclic lactone in an analogous composition. MPEP 2144.05 addresses routine optimization procedure as it relates to patentability:

> "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)."

Claims 1 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennessy *et al.* (US 5,840,324) in view of IVS Annual Index of Veterinary Products (see IDS, 05/31/2007).

Claims 1, 10, and 11 are rejected for the reasons set forth in the 102 rejection above. Hennessy *et al.* teach the content and limitations of claim 1 which is drawn to a method of reducing parasites in animals by introducing a single delivery device containing two or more different anthelmintic compounds as an intra-ruminal bolus. Also, as claims 10 and 11 are drawn to benzimidazole as the anthelmintic compound and to albendazole as the benzimidazole species, Hennessy *et al.* previously taught both of these active agents in the analogous composition (column 9, line 47).

In regard to the content of instant claim 12 which limits the dosage to a value between 3.0 and 5.0 mg/kg/day, Hennessy *et al.* do not teach a quantitative effective or desired dosage of albendazole.

One of ordinary skill in the art at the time of the invention would have been motivated to consult the IVS Annual Index of Veterinary Products in order to ascertain an effective dosage of albendazole. Additionally, Hennessey *et al.* did in fact teach the content of independent claims 10 and 11, which are drawn to benzimidazole as the anthelmintic compound and to albendazole as the benzimidazole species. Hennessey *et al.* previously taught both of these active agents in the analogous composition (column 9, line 47). So, in order to effectively implement a quantity of the active agent albendazole, a consultation of The IVS Annual Index of Veterinary Products would have shown that albendazole sheep is an effective antiparasitic agent with an effective dosage quantity delivering 4.75 mg/kg of albendazole. This value lies within the instantly claimed range of 3.0 to 5.0 mg/kg for a single dosage quantity. Because one of

ordinary skill in the art would have performed routine optimization procedures in order to maximize desired functions of the claimed methodology, the previously disclosed dosage quantity of 4.75 mg/kg of albendazole would have rendered the content of the instant claim to have been *prima facie* obvious. See MPEP 2144.05 regarding the patentability of routine optimization practices.

Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennessy *et al.* (US 5,840,324) in view of Sanyal *et al.* (Vet. Res. Comm. *20*, 1996, 461-468).

Hennessy *et al.* teach the content and limitations of claim 1 which is drawn to a method of reducing parasites in animals by introducing a single delivery device containing two or more different anthelmintic compounds as an intra-ruminal bolus. Therefore, claim 1 is rejected under 35 U.S.C. 102 for the reasons set forth above.

Claim 13 is drawn to the anthelmintic identity of tricalbendazole, a member of the benzimidazole family of anthelmintics. Tricalbendazole commonly is known in the art as an antiparasitic agent, particularly effective against fluke. Although Hennessy *et al.* do not specifically name tricalbendazole as a particular effective benzimidazole, Sanyal *et al.* teach triclabendazole as an effective low-level intraruminal anti-fluke anti-parasite agent. On account of this teaching, one of ordinary skill in the art would have been motivated to implement the active ingredient of triclabendazole into the instantly disclosed composition, thereby rendering the implementation of triclabendazole as an active anti-parasite to

have been *prima facie* obvious. That is, one of ordinary skill in the art at the time of the invention reasonable would have expected continued success from implementing the known anti-parasite which is triclabendazole into an anti-parasitic composition relying on anthelmintic active agents.

Claims 1, 15, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennessy *et al.* (US 5,840,324) in view of Lewis (US 5,733,566).

Hennessy *et al.* teach the content and limitations of claim 1 which is drawn to a method of reducing parasites in animals by introducing a single delivery device containing two or more different anthelmintic compounds as an intra-ruminal bolus. Therefore, claim 1 is rejected under 35 U.S.C. 102 for the reasons set forth above.

Claims 15 and 16 respectively limit the release of active agents to a period which is between 5 and 10 days, and to a period which is between 6 and 8 days, respectively. Although Hennessy *et al.* teach controlled release of active agents for antiparasite functions, Hennessy *et al.* do not limit the release time period to values matching those instantly claimed. However, Lewis teach an analogous invention preferably which relies on anthelmintic active agents for parasite control; Lewis' invention provides for durations of action, where the duration ranges from less than a week to several months depending upon the type of microsphere delivery form selected. So, one of ordinary skill in the art at the time of the invention would have expected reasonable success from limiting the

temporal period to a range which was included by the prior teachings of Lewis. Lewis continues, "In a preferred embodiment, the microspheres are designed to afford antiparsitic effect in animals over a period of a few days to one year," (column 12, line 54). For the broad antiparasite formulations and methods claimed, a correspondingly broad time range is claimed, however, one of ordinary skill in the art at the time of the invention would have been motivated to utilize this temporal starting point in order to manipulate the bolus or polymer encapsulation type as suggested in order to control the release and effective quantities of active agents. Therefore, limiting the release of the active agents to a time period between 5 and 10 days or to a time period between 6 and 8 days would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention. Additionally, the instant specification does not detail why or how the particular time periods instantly claimed offer improvements over the prior teachings such as those of Lewis.

Claim 18 is drawn to the limitation of the chosen parasite to one which remains an ectoparasite selected from a variety of given groups. The formulations and corresponding methods as disclosed by Hennessy *et al.* do not explicitly teach anti-parasite active which is limited to or inclusive of ectoparasite activity. However, Lewis teaches the controlled release of antiparasitic agents in animals in a formulation and method which parallels that of Hennessy *et al.* as well as the instant invention. On account of the similar components and functions, one of ordinary skill in the art at the time of the invention would have been motivated to consider the broader target parasites as disclosed by Lewis

when compared with the relatively narrow target parasite groups as outlined by Hennessy *et al.*, particularly since both teachings rely on anthelmintic active agents. More specifically, Lewis discloses preferred embodiments of antiparasite active agents which are anthelmintics (column 6, line 26) capable of controlled release (column 5, line 28). Further, Lewis discloses ectoparasitic agents which are effective against species which include ticks, mites, lice, fleas, *et cetera* (column 3, line 55). On account of this broad application of anthelmintic active agents, one of ordinary skill in the art would have found the implementation of Lewis' teachings with the analogous teachings of Hennessy *et al.* to have rendered anthelmintic activity against ectoparasites to have been *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3 provisionally are rejected on the ground of nonstatutory double patenting over claims 1-4 and 20 of copending Application No. 11908708. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Although the compared claims are not identical, they are not patentably distinct from each other. The methods described in the compared claims comprise the same components and general process steps. Further, the limitations as cited in the instant application are claimed in the copending claims as described below. Accordingly, the copending claims from the copending reference are subject to obviousness-type double patenting.

Claim 1 of the instant invention is drawn to a method of reducing parasites in animals by introducing a single delivery device containing two or more different anthelmintic compounds to an animal; also, the delivery device is an intra-ruminal bolus configured to release an effective amount of active agents each day for a period of between 3 and 14 days. All of the features of instant claim 1 are included in copending Application No. 11908708 in claims 1-4. Claim 1 of the copending application outlines a composition included in the instantly claimed method, although the copending application further limits the formulation components and expands the time period of active agent release. The following dependent claims are rejected for provisional obviousness type double patenting further in view of the rejection of instant, independent claim 1 as described above.

Claim 3 of the instant invention is drawn to the same inventive concept as claim 20 of the copending application. Both claims are drawn to the substantially continuous rate of release of an active agent.

Likewise, Claims 15 and 16 of the instant invention are drawn to the same subject matter as claims 1 and 2 of the copending application, where the duration of active agent release is obvious in view of the copending application and vice versa.

This is a provisional obviousness-type double patenting rejection because the copending claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Audrea Buckley/
Patent Examiner, Art Unit 4131

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